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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,636	01/25/2002	J. Kenneth Koster JR.	KOSTER-02	9844

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EXAMINER

ROBERTS, PAUL A

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 03/12/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/056,636

Applicant(s)

KOSTER, J. KENNETH

Examiner

Paul Roberts

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2003.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
4a) Of the above claim(s) 14-16 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-13 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 1/25/02 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/25/02.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-13, drawn to an apparatus for anastomosis, classified in class 606/145.
- II. Claims 14-16, drawn to a method of performing anastomosis, classified in class 606/153.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case there are alternate uses for the apparatus of group I. The apparatus could be used to puncture the skin.

During a telephone conversation with Thomas Saiti on February 24, 2004 a provisional election was made without traverse to prosecute the invention of group I, claims 1-13.

Affirmation of this election must be made by applicant in replying to this Office action.

Claim 14-16 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Oath/Declaration

1. The declaration appears to be missing from the file. Please a copy of the originally filed declaration with the response to this Office action.

Specification and Drawings

The disclosure is objected to because of the following informalities: Numerous errors were found between the specification and the corresponding figures. For example on page 6 element 33 is used to describe the shaft and the handle, no connection means 19 is shown in the drawings, no punch assembly 30 is shown, and element 18 is not in the specification. Thus the drawings do not comply with 37 CFR 1.84(p)(4). Please ensure all elements in the drawings are in the specification and vice versa, and that two elements aren't referenced by the same number. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Donohoe et al. (Donohoe) 2002/0082626. Donohoe discloses an anastomosis tool with a means to produce an opening in an aortic wall (12), said means comprising in combination a punch assembly (26), and a cutting sleeve (28) disposed within a housing (18) which has a central bore. Looking at figure 6, Donohoe discloses a lateral shaft assembly (14) connected to said housing, said lateral

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shaft having a lateral bore communicating with said central bore. The lateral shaft is capable to receive a vein graft such that said vein graft may be advanced through said lateral shaft.

3. Regarding claim 2, the distal section (16) is part of the means to seal the opening after said opening is produced.

4. Regarding claim 3, the cutting sleeve comprises a distal portion and a proximal portion, wherein said punch assembly and proximal portion of the sleeve is retractable, and wherein said lateral bore freely communicates with said central bore when said punch assembly and said proximal portion of said cutting sleeve is retracted.

5. Regarding claim 4, the punch assembly retains a portion of the aortic wall when the wall is punched and the sleeve retracted.

6. Regarding claim 5, the distal section (16) is part of the means to seal the opening after said opening is produced.

7. Regarding claim 6, the cutting sleeve assembly comprises a means to advance the cutting sleeve relative to said punch assembly for producing said opening. [0048]

8. Regarding claim 7, the proximal portion (comprises 30 and 14) is retractable from the distal portion 16.

9. Regarding claim 8, the shaft comprises a cap (40), which is inherently capable of receiving a balloon catheter.

10. Regarding claim 9, Donohoe discloses an anastomosis device for joining a vein graft to an aorta wall comprising: an elongated housing (18) comprising a central bore; an annular cutting sleeve (12, fig 4) assembly disposed within said central bore, wherein at least a portion of said cutting sleeve assembly is retractable relative to at least a portion of said housing; a

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retractable punch assembly (26) disposed within said cutting sleeve assembly, wherein said punch assembly is retractable relative to at least a portion of said housing; a lateral shaft (92, figure 13B) obliquely joined to said housing and comprising a lateral bore; wherein said retractable portion (14 and 12 of figure 13b) of said cutting sleeve assembly and said retractable punch assembly are retractable beyond said lateral bore such that said lateral bore is in communication with said central bore when said retractable portion of said cutting sleeve assembly and said retractable punch assembly are retracted, whereby a vein graft may be advanced through said lateral bore and said central bore.

11. Regarding claim 10, only the proximal portion is retractable.
12. Regarding claim 11, the cutting sleeve can be advanced relative to the punch assembly.
13. Regarding claim 12, in figure 13b there is a line dividing housing 18 shown near the label. This housing is not designed to be separated, however it is capable of being separated, and is therefore separable.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

2002/0077637; 5944730; 6080173; 5690662; 2003/0195535; 6673088; 5910153; 5893369; 5676670 (all US disclosures) are all anastomosis punches similar to the one the applicant has disclosed.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Roberts whose telephone number is 703-305-8122. The examiner can normally be reached on M-F, 7:30-5:30 (Second Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Paul Roberts
February 24, 2004



MICHAEL J. MILANO
SUPERVISORY PATENT EXAMINER
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